which require the At-Rest pulse oximetry test to be conducted when the patient is at rest. PPS' knowing reliance on prescriptions and CMNs based on such falsified oximetry results to seek payment from Medicare and/or Medi-Cal for such equipment or service, was fraudulent.

- **PPS Provided Free Use of Oximeters to Physicians For Referrals**

133. During the relevant period, at PPS' direction and with PPS' knowledge and consent, in an effort to boost referrals for oxygen business, PPS engaged in a "loaner" arrangement with physicians in which PCCs "loaned" a PPS-owned pulse oximeter to such physicians' offices without charge to the physician. Depending upon their sales success, PCCs had access to a greater number of "loaner" oximeters. The PCCs showed physicians and/or their staff how to use the oximeter to conduct pulse oximetry tests on patients in their offices. One of PPS's purposes in running the "loaner" program was to cause the physicians to prescribe, and sign CMNs for, PPS oxygen equipment and supplies for their patients. When a physician did not refer a sufficient number of patients to PPS for home oxygen service, the assigned PCC took back the "loaner" oximeter.

134. During the relevant period, among others, PCC Kelly Guerrero provided "loaner" oximeters to Dr. Jaime Cortes in Oakland, CA, Drs. Robert L. Wu and Ronald L. Rubenstein of Bay Area ENT Medical Group in San Leandro CA, and Drs. Herbert Weingard, Christi Cheng, and Douglas Zhang of Family Medical Group in San Leandro, CA. PCC Chris Garrity provided "loaner" oximeters to Dr. Deepti Saxena in Fremont, CA. PCC Kristel Rochios provided "loaner" oximeters to Dr. Norman Banks in San Pablo, CA, and Dr. Hsu Hwei Jung in San Pablo, CA. PCCs reported daily to District Manager Karen Vickrey which physicians had "loaner" oximeters. The physicians receiving PPS "loaner" oximeters to test patients at their offices frequently wrote prescriptions and CMNs for PPS oxygen equipment and supplies for

Medicare and Medi-Cal patients, and PPS often billed Medicare and Medi-Cal for such equipment and supplies.

135. PPS' provision of a "loaner" pulse oximeter without charge to physicians essentially paid for the cost of the pulse oximetry test in violation of the 2009 Oxygen LCD ("the qualifying blood gas study may not be paid for by any supplier"). PPS thus violated its PPS Medicare Certification that it would comply with Medicare program instructions.

136. Further, PPS' provision of "loaner" pulse oximeters without charge to physicians was a transfer of a valuable item for free to physicians who used it to provide services to their Medicare and/or Medi-Cal patients for which they were paid, whether the physician charged separately for the oximetry test or the charge was bundled with the charge for the physician's other services to that patient. Moreover, PPS' provision of the valuable item was done with the intent, and for the purpose, of obtaining prescriptions and CMNs from such physicians for PPS oxygen equipment and supplies, many of which were then billed to Medicare or Medi-Cal.

137. Under 42 U.S.C. Section 1320-7a(i)(6), "remuneration" includes "transfers of items or services for free or for other than fair market value." PPS' provision of an oximeter free of charge for use by physicians is "remuneration." *Accord, e.g.* OIG Advisory Opinion No. 07-08 (providing a free oximetry test constitutes "remuneration"). 42 U.S.C. Section 1320a-7b(b)(2) imposes criminal penalties on any person who "knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program." PPS offered physicians free use of oximeters to induce those physicians to refer patients to PPS for the

furnishing of oxygen equipment and services that were paid for by the Medicare, Medicaid or Medi-Cal programs.

138. By violating the AKS, PPS violated its PPS Medicare Certification and its PPS Medi-Cal Certification that it would comply with applicable federal laws.

- **PPS Fraudulently Performed Oximetry Testing on Patients**

139. During the relevant period, at PPS' direction and with PPS' knowledge and consent, PCCs also encouraged physicians' offices to call the PCC when the physician or staff wanted a pulse oximetry test conducted for a patient at the physician's office. Many times the PCC directly conducted pulse oximetry tests in the physician's office, using either a PPS "loaner" oximeter already at the physician's office or a PPS oximeter that the PCC brought along. The PCC then provided the pulse oximetry test results to physicians' staff. Some of these oximetry tests resulted in physicians writing patient prescriptions for PPS oxygen equipment and service, for which PPS billed Medicare or Medi-Cal.

140. Frequently during the relevant period, and at PPS' direction and with PPS' knowledge and consent, PPS PCCs, at physicians' requests, also conducted pulse oximetry tests on patients at clinics, nursing homes, and in their homes. The PCCs then provided the pulse oximetry test results to physicians' staff and erased the data from the oximeter. Some of these oximetry tests resulted in physicians writing patient prescriptions and CMNs for PPS oxygen equipment and supplies, for which PPS billed Medicare or Medi-Cal.

141. During the relevant period and among others: PCC Kelly Guerrero performed pulse oximetry tests on Medicare and/or Medi-Cal patients in the offices of Dr. Jaime Cortes in Oakland, CA, at the AJ Thomas Clinic in Oakland, CA, at the offices of Dr. Andrea Anderson in Alameda, CA and at the Oakridge Care Center on Fruitvale Avenue, Oakland, CA. PCC Kristel

Rochios performed pulse oximetry tests on Medicare and/or Medi-Cal patients in the offices of Dr. Norman Banks in San Pablo, CA, in the offices of Dr. Hsu Hwei-Jung in San Pablo, CA, and at the West Berkeley Family Practice in Berkeley, California. PCC Lydia Carson performed pulse oximetry tests on Medicare and/or Medi-Cal patients at the Martinez Family Practice Center in Martinez, CA, at the Contra Costa Regional Medical Center in Martinez, CA, and in patients' homes. PCC Rebecca Leibert performed pulse oximetry tests on Medicare and/or Medi-Cal patients in the offices of Dr. Richard E. Oliver of the Chabot Nephrology Medical Group, who has offices in Hayward and Pleasanton. PCC Amber Davis performed pulse oximetry tests on Medicare and/or Medi-Cal patients in the offices of doctors she serviced in Walnut Creek, CA. PCC Chris Garrity performed pulse oximetry tests on Medicare and/or Medi-Cal patients in the offices of Dr. Deepti Saxena in Fremont, CA. District Manager Karen Vickrey was aware of and encouraged this conduct, considering it a sign of "trust" from the referring physicians.

142. When PPS PCCs performed pulse oximetry tests, they violated the 2009 Oxygen LCD and the Oxygen NCD. PPS thus violated its PPS Medicare Certification that it would comply with Medicare program instructions.

- **PPS Fraud in Conducting Overnight Home Pulse Oximetry Testing**

143. During the relevant period, and at PPS' direction and with PPS' knowledge and consent, PPS PCCs repeatedly violated Medicare program instructions governing the conduct of overnight home pulse oximetry tests. PPS' conduct made a mockery of every protection that CMS included in the Oxygen NCD, Transmittal 173, and the Oxygen LCD.

144. During the relevant period, at PPS' direction and with PPS' knowledge and consent, PCCs pushed to have as many Medicare patients receive overnight home pulse oximetry

tests as possible. PPS wanted such patients to undergo overnight home pulse oximetry testing—and for PCCs to get into patients' homes – for at least three reasons that advanced its business interests:

a. First, patients could, and often did, qualify for home oxygen service under applicable Medicare criteria, leading to a prescription and CMN for PPS oxygen equipment and supplies;

b. Second, even if patients did not qualify based on the overnight test, PCCs could, and did, use information from the test and gathered from the patients during the PCCs' visits to the patients' homes, to convince physicians that the patients were short of breath during normal activities in their living environment and that such patients should be given an "At-Rest" test immediately following exercise in an effort to qualify them for home oxygen service. Physicians often agreed to another "At-Rest" test, conducted by PPS, that "qualified" the patient for home oxygen service and lead to a prescription and CMN for PPS oxygen equipment and supplies.

c. Third, PCCs could, and did, use information from the test and gathered from the patients during the PCCs' visits to the patients' homes, to convince physicians that such patients had trouble sleeping and should undergo a PSG sleep test for OSA. Physicians often then prescribed such a sleep test and such sleep tests frequently lead to a prescription for PPS sleep therapy products. Because the PSG sleep test also records arterial oxygen saturation, the sleep test also provided another chance to qualify a patient for home oxygen service.

145. During the relevant period, PPS PCCs promoted overnight home pulse oximetry tests for Medicare patients through a variety of schemes.

a. First, PCCs approached patients in physicians' waiting rooms, hospitals and clinics, encouraging them to ask their doctor for pulse oximetry testing.

b. Second, PCCs approached physicians and their staff to recommend that physicians prescribe an overnight home pulse oximetry test for a patient.

c. Third, along with the "loaner" PPS oximeters, PPS provided a "Pulse Oximetry Log" that provides a check box entitled "If 93% or less, Overnight Oximetry ordered." PPS encouraged physicians' staff to follow the Pulse Oximetry Log.

d. Fourth, when PCCs presented a PPS form prescription to a physician, the PCCs consistently checked off authorization for "Pulse Oximetry Testing." When PCCs delivered PAP devices or nebulizer equipment to patients' homes, the PCCs told the patients that their doctor wanted them to undergo an overnight oximetry test.

e. Fifth, for patients then-currently receiving a PPS non-oxygen service, PCCs created a reason to visit such patients at home, e.g. delivery of supplies that were available to PCCs for "marketing." During those home visits, PCCs told patients that they should undergo an overnight oximetry test to provide more information to their doctor, even though no physician had yet prescribed such a test.

146. During the relevant period, once PCCs successfully got inside Medicare patients' homes, they promoted additional PPS business as follows::

a. PCCs asked the patient a series of questions designed to gather information the PCC could use to convince a physician to prescribe a PSG sleep test or additional oximetry tests (if the patient did not qualify with the overnight oximetry test), and to establish a quality of life that required home oxygen service, sleep therapy or both. PCCs filled out a PPS "Patient Visit Form" for each patient visit.

b. PCCs then explained to the patient how to use the overnight oximetry equipment, showed how to use it on himself/herself, and then put it on the patients to show them how to do it. The PCCs answered questions by the patients about the test and the test equipment.

c. PCCs the presented the patients with two documents, the "PPS Informational Pulse Oximetry Instructions" and a form from an IDTF for oximetry testing. For the PPS San Leandro office, the favored IDTF was "Oxi-Techs" in Stockton, CA, and patients were given an Oxi-Techs form. The Oxi-Techs form has patient and insurance information on the front, which was completed by the PPS PCC, and instructions for oximeter use on the back. The patient was asked to sign the Oxi-Techs form, which authorized payment to Oxi-Techs by Medicare, committed the patient to pay for charges not covered by health care benefits (such as co-payments), and authorized Oxi-Techs to provide a copy of the test results to the "DME provider listed above," which was PPS.

d. Despite the Oxi-Techs form, PCCs often told patients that the overnight oximetry test was "complimentary" and part of the PPS service. The PPS Informational Pulse Oximetry Instructions state that the "service is complimentary. Neither the patient, the insurance nor the physician will be charged ...." In fact, when the results were sent to Oxi-Techs, the IDTF billed Medicare, which in turn charged patients a co-payment.

e. PCCs then told patients to record when the test started and stopped on the Oxi-Techs form, to put the equipment and form back in the bag it came in the next morning, and put the bag on the porch where the PCC would collect it.

147. After PCCs collected the home pulse oximetry equipment from the patients' homes, how they handled the data would depend on how they had gotten the patient to undergo the overnight test. If a physician had prescribed the overnight oximetry test, the PCCs uploaded the test results to Oxi-Techs (sometimes only after PPS accessed the results directly), which would then lock the data and provide a copy to both the physician and PPS. The PCC would review the test results and, if the results indicated that the patient qualified for oxygen service, the PCC would order oxygen equipment for the patient. The PCC then would notify the physician or staff that the patient had qualified, that the PCC had ordered the necessary oxygen equipment so that the patient could have it as soon as possible, and that the PCC would deliver a prescription for the physician to sign prescribing home oxygen service for the patient. PPS then prepared the prescription on a PPS prescription form, including the "diagnosis" (COPD, Emphysema, Chronic Bronchitis, Chronic Asthma, CHF or other) that qualified the patient for home oxygen under Medicare program instructions. After the physician signed the prescription, and the home oxygen equipment was delivered to the patient, then PPS provided a CMN to the physician for PPS home oxygen service.

148. If, however, PPS PCCs had convinced a Medicare patient receiving a PPS non-oxygen service to undergo an overnight oximetry test without a doctor's prescription, the PCCs

followed a slightly different path. After collecting the oximetry equipment from such a patient's home, the PCC accessed the test results, uploaded them into PPS's "NPF" system, and reviewed the results. If the results would qualify the patient for home oxygen service, then the PCC prepared a prescription for overnight oximetry testing (and sometimes for home oxygen service with the physician told it would be filled "only if the patient qualifies") and presented it to the patient's physician for signature. Once the physician signed the prescription, the PCC then uploaded the results to the IDTF (Oxi-Techs), for which the PCC already had a form signed by the patient. After Oxi-Techs locked the data and provided it to the physician and PPS, the PCC then ordered PPS home oxygen equipment for the patient (only sometimes after getting a verbal order from the physician) and reported to the physician that the patient had qualified for home oxygen service, which PPS was in the process of providing. PPS the prepared another prescription (if needed), later followed by a CMN, for the physician's signatures.

149. The foregoing conduct by PPS PCCs violated nearly every aspect of the Medicare program instructions set forth in the 2009 Oxygen NCD, Transmittal 173 and the 2009 Oxygen LCD, which were intended to ensure that DME suppliers were not involved in the overnight home oximetry testing due to their inherent conflict of interest.

150. First, during the relevant period, with the physicians' consent, PPS selected the IDTF that received the overnight pulse oximetry test results on Medicare patients of, among others, Drs. Jaime Cortes, Robert Wu, Ronald Rubenstein, Herbert Weingard, Christi Cheng, Douglas Zhang, Norman Banks, Richard Oliver, Deepti Saxena, R.S. Rajah, Paul Robinson, Nabil Abudayeh, Kenneth Rothman, Haramandeep Singh, Man Kong Leung, and Hsu Wei-Jung. For at least PCCs operating from the San Leandro Center under District Manager, PPS always selected the IDTF. In so doing, PPS violated the 2009 Oxygen LCD ("The beneficiary's treating

physician has contacted the IDTF to order an overnight pulse oximetry test before the test is performed"). Thus, PPS violated its PPS Medicare Certification that it and its employees would comply with Medicare program instructions.

151. Second, during the relevant period, PPS PCCs including but not limited to PCCs Kelly Guerrero, Kristel Rochios, Amber Davis, Alicia Pierce, Rebecca Leibert, Chris Garrity and Matt Hucek personally delivered the pulse oximeters to Medicare patients' homes, verbally instructed them how to use the test equipment, provided PPS-created written instructions on the operation of the test equipment, demonstrated how to use the test equipment on themselves and the patient, and answered patient questions about the test and the test equipment. . Such conduct was known to and approved by District Manager Karen Vickrey and Regional Manager Pete Flath. Ms. Vickery insisted that PCCs delivering the overnight pulse oximetry test equipment to patients instruct and show such patients how to use the pulse oximeter for the overnight test to avoid any need for a PCC to return to the patient's home to repeat the test, which would take PCC extra time and generate mileage reimbursement claims by the PCC to PPS.

152. In so doing, PPS violated the 2009 Oxygen LCD ("The test is performed under the direction and/or instruction of a Medicare-approved IDTF. Because it is the beneficiary who self-administers this test, the IDTF must provide clear written instructions to the beneficiary on proper operation of the test equipment and must include access to the IDTF in order to address other concerns that may arise. The DME supplier may not create this written instruction, provide verbal instructions, answer questions from the beneficiary, apply or demonstrate the application of the testing equipment to the beneficiary, or otherwise participate in the conduct of the test") (emphasis added), and Transmittal 173 ("Because CMS Pub.100-3, section 240.2.C prohibits

DME suppliers from performing tests, the DME supplier may not create this instruction nor participate in the conduct of the test.") (Emphasis added). Thus, PPS violated its PPS Medicare Certification that it and its employees would comply with Medicare program instructions.

153. Third, where PCCs convinced Medicare patients receiving PPS-non-oxygen services to undergo an overnight pulse oximetry test without a prescription from the patient's treating physician, PPS PCCs violated the 2009 Oxygen LCD's requirement that "[t]he beneficiary's treating physician has contacted the IDTF to order an overnight pulse oximetry test before the test is performed." (Emphasis added). Among others, PCCs Kelly Guerrero, Kristel Rochios, Amber Davis, Alicia Pierce, Rebecca Leibert, Chris Garrity and Matt Hucek engaged in such conduct. Such conduct was known to and approved by District Manager Karen Vickrey. By such conduct, PPS violated its PPS Medicare Certification that it and its employees would comply with Medicare program instructions.

154. Fourth, where PCCs convinced Medicare patients receiving PPS-non-oxygen services to undergo an overnight pulse oximetry test without a prescription from the patient's treating physician, and accessed the test results before uploading them to the IDTF, the PCCs violated the following requirement in the 2009 Oxygen LCD: "The test unit is sealed and tamper-proof such that test results cannot be accessed by anyone other than the IDTF who is responsible for transmitting a test report to the treating physician. The DME supplier may use related technology to download test results from the testing unit and transmit those results to the IDTF. In no cases may the DME supplier access or manipulate the test results in any form." Among others, PCCs Kelly Guerrero, Kristel Rochios, Amber Davis, Alicia Pierce, Rebecca Leibert, Chris Garrity and Matt Hucek engaged in such conduct. Such conduct was known to and

approved by District Manager Karen Vickrey. By such conduct, PPS violated its PPS Medicare Certification that it and its employees would comply with Medicare program instructions.

- **PPS Fraudulently Solicited Oximetry Testing To Increase Oxygen Sales**

155. During the relevant period, and at PPS' direction and with PPS' knowledge and consent, during visits to physicians' offices, every PCC from the PPS San Leandro office approachedpatients in the waiting room that seemed "short of breath" or otherwise a potential customer for PPS products. They recommended that the patients ask their physicians for testing to qualify them for the many benefits of oxygen and sleep therapy. The PCCs had "sold" the potential patients on these benefits while they sat in the waiting rooms with them.

156. During the relevant period, and at PPS' direction and with PPS' knowledge and consent, every PCC from the PPS San Leandro office also spoke to physicians' staff about patients in the waiting room that the PCCs had talked to about difficulties sleeping or shortness of breath, or which the PCCs claimed looked like they were "out of breath." These patients were often the old, the feeble and the weak and they were susceptible to the suggestions of the PCCs. After harvesting this information from the waiting room, PCCs recommended to the physician and/or staff that such patients be tested to determine their need for home oxygen. Physicians often then ordered oximetry testing that resulted in prescriptions and CMNs for PPS oxygen equipment and services, for which PPS billed Medicare and/or Medi-Cal.

157. During the relevant period, at PPS' direction and with PPS' knowledge and consent, PPS PCCs sought and obtained access to hospital patient discharge calendars and/or discharge plans to hunt for patients who could be referred to PPS for oximeter testing, home oxygen service, CPAP or nebulized medicine. PCC Matt Hucek, in PPS' Modesto office, was PPS' top salesman and was held up as a model for other PCCs. Mr. Hucek's wife is the chief of

the residency program at Stanislaus County Memorial Hospital. Mr. Hucek reviewed patient discharge calendars and plans at Stanislaus County Memorial Hospital. If a discharge plan said a patient needed oxygen or CPAP, Mr. Hucek would either ask the discharge planner to ask the responsible physician, or ask the physician directly, to write a prescription and CMN for PPS products. If patient records included symptoms that suggested a potential need for oxygen, Mr. Hucek would ask the physician to write a prescription for an overnight oximetry test. Mr. Hucek also walked the hospital floors and talked to patients about their symptoms. If a patient looked like a potential candidate for oxygen or sleep therapy, Mr. Hucek encouraged the patient to ask a doctor to prescribe oxygen or CPAP, and/or Mr. Hucek would make such a recommendation to the responsible physician directly. At PPS, this conduct was known as "doing rounds." Among other PCCs engaged in similar conduct, PCC Lydia Carson engages in similar conduct at Sutter VNA in Martinez, CA, PCC Kelly Guerrero engages in similar conduct at Highland Hospital in Oakland, CA, and PCC Rebecca Leibert engages in similar conduct at Valley Care Medical Hospital in Pleasanton, CA. Such conduct is a common practice among PPS PCCs. District Manager Karen Vickrey was aware of and encouraged this conduct.

158. PPS also encouraged PCCs to attempt to sell oxygen service to all patients receiving PPS sleep therapy. The PPS Sleep Therapy & OSA training manual notes: “There are two common opportunities to find oxygen patients while selling CPAP services. 1. When screening for a sleep study with an overnight pulse oximetry, check to see if the patient qualifies for oxygen. If the patient meets qualification guidelines, use patient stories (or parallel stories) to talk to the referral source about: Getting the patient on oxygen immediately to reduce the number of desaturations. … 2. A CPAP patient that is not feeling better with therapy. … If the patient reports feeling no better, offer to facilitate an overnight pulse oximetry with the patient on a

CPAP to determine their oxygen saturation levels." PCCs also were informed in ride-alongs and in weekly sales meetings that they should put in the effort it took to make sure all sleep therapy patients undergo oximetry testing to qualify them for PPS oxygen service.

159. PPS PCCs Lydia Carson, Chris Garrity, Amber Davis, Rebecca Leibert, and Kelly Guerrero, among others, often delivered PPS CPAP devices to patients for whom such devices were prescribed to address OSA so that they could implement PPS' instructions to sell oxygen services to such patients. During these deliveries, PCCs questioned patients about their health and attempted to convince the patients that they might need oxygen service also and should ask for oximetry testing. These PCCs also contacted the patients' physicians to recommend that such patients be prescribed oximetry testing and/or oxygen service.

160. Such conduct violated the admonition in the Noridian June 2006 Bulletin: "Suppliers are cautioned that sleep oximetry testing must be based on a request that is initiated by the treating physician. It is inappropriate for a supplier or IDTF to initiate a contact with the physician either directly or through the beneficiary to request, suggest or otherwise seek an order for an oximetry test." Thus, PPS and its employees violated PPS' certification that it would comply with Medicare program instructions.

161. Congress' intent to protect Medicare beneficiaries from DME suppliers' sales pitches is apparent in 42 U.S.C. § 1395m(a)(17), which forbids DME suppliers from soliciting Medicare patients by telephone. When CMS issued Transmittal 173, allowing DME suppliers to deliver oximetry equipment to patients but barring them from providing instructions or answering questions about the equipment, CMS did not open the door to DME supplier representatives questioning patients and selling them on additional DME services that are then billed to Medicare. PPS PCCs sales tactic of delivering either oximetry testing equipment or

CPAP devices, and attempting to sell patients on the need for additional PPS equipment once inside the patient's home, violates Medicare program instructions as set forth in the Noridian June 2006 Bulletin, which implemented the intent of Congress.

- **PPS Fraudulently Manipulated Completion of CMNs**

162. Medicare rules require that a physician complete a Certificate of Medical Necessity, CMS-484 Oxygen, before Medicare will pay for home oxygen. The Oxygen NCD states: "Initial claims for oxygen services must include a completed Form CMS-484 (Certificate of Medical Necessity: Oxygen) to establish whether coverage criteria are met and to ensure that the oxygen services provided are consistent with the physician's prescription or other medical documentation."

163. Congress directly addressed its concern that DME suppliers, which have a financial self-interest in selling DME equipment to Medicare patients, were taking too great a role in completing Certificates of Medical Necessity for DME. Through the Social Security Act Amendments of 1994, Congress specifically limited the information that suppliers could provide for Certificates of Medical Necessity. 42 U.S.C. Section 1395m(j)(2)(A) provides:

> Effective 60 days after October 31, 1994, a supplier of medical equipment and supplies may distribute to physicians, or to individuals entitled to benefits under this part, a certificate of medical necessity for commercial purposes which contains no more than the following information completed by the supplier:
>
> (I) An identification of the supplier and the beneficiary to whom such medical equipment and supplies are furnished.
>
> (II) A description of such medical equipment and supplies.
>
> (III) Any product code identifying such medical equipment and supplies.

(IV) Any other administrative information (other than information relating to the beneficiary's medical condition) identified by the Secretary. (Emphasis added).

164. The Medicare CMN for Oxygen contains Sections A through D. Section A contains identifying information for the patient, physician and supplier, and may be completed by the DME supplier. Section C describes the DME equipment ordered and its cost, and may be completed by the DME supplier. Section B contains medical and prescription information. Form CMS-484 plainly states on its face: "Information in This Section May Not Be Completed by the Supplier of the Items/Supplies." The Form CMS-484 Instructions also state: "May not be completed by the supplier." Section D is the physician's signature.

165. In addition to Form CMS-484 itself, the Oxygen NCD also states that Section B of the CMN is to reflect the physician's judgment of the medical necessity, not the views of the financially-interested DME supplier ("The medical and prescription information in section B of Form CMS-484 can be completed only by the treating physician, the physician's employee, or another clinician (e.g., nurse, respiratory therapist, etc.) as long as that person is not the DME supplier. Although hospital discharge coordinators and medical social workers may assist in arranging for physician-prescribed home oxygen, they do not have the authority to prescribe the services. Suppliers may not enter this information.").

166. The Noridian DME MAC Jurisdiction D Supplier Manual, Chapter 4, regarding the Certificate of Medical Necessity/DME Information Form provides: "The Social Security Act was amended in 1994 to specify the types of information that suppliers may provide to physicians in a CMN. These are limited to an identification of the supplier and beneficiary, a description of the equipment and supplies being ordered, procedure codes for the equipment and

supplies, and other administrative information not related to the medical condition of the beneficiary." (Emphasis added).

167. DME suppliers and physicians are permitted to use cover letters to communicate, under both CMS (CMS Pub. 100-08, Medicare Program Integrity Manual, Chapter 5, Section 5.3.2) and Noridian (DME MAC Jurisdiction D Supplier Manual, Chapter 4. CMS and Noridian, however, did not authorize DME suppliers to violate Congress' admonition that DME suppliers are not to provide "information relating to the beneficiary's medical condition." 42 U.S.C. Section 1395m(j)(2)(A).

168. When PPS PCCs successfully obtained a referral for oxygen equipment and services, PPS Customer Service Representatives ("CSRs"), including prepared and provided the referring physician with a CMN for Oxygen. PPS CSRs completed Section A and Section C. PPS CSRs also prepared and attached to the CMN a "cheat sheet" that contained the medical information about the patient that the CSRs believed was necessary to qualify the patient for home oxygen under Medicare rules. In essence, the PPS CSRs completed Section B of the CMN, but put the text on an attached "cheat sheet" for the physician's staff to copy into Section B. In so doing, PPS violated 42 U.S.C. § 1395m(j)(2)(A), the Oxygen NCD, Noridian DME MAC Jurisdiction D Supplier Manual, and the CMS Form 484 Instructions, among other Medicare rules. Thus, PPS violated its certification that it and its employees would comply with Medicare rules.

VIII. FALSE AND FRAUDULENT CLAIMS AND STATEMENTS

169. Defendants Braden Partners, LP doing business as PPS, Teijin-Pharma USA LLC also doing business as PPS, and Peter B. Kelly and Chad Heath Martin as general partners of

Braden Partners, LP, are each jointly and severally liable for the conduct of PPS set forth in this Complaint.

170. The PPS Defendants, by and through their officers, agents, and employees, authorized and encouraged the actions of its various officers, agents, and employees to take the actions set forth in this Complaint.

171. As set forth in more detail in the preceding paragraphs, PPS knowingly offered certain physicians and clinics conducting PSG sleep tests, including the Sleep Test Defendants, valuable remuneration consisting of referrals and recommendations for PSG sleep testing of Medicare or Medi-Cal patients, for which such physicians were paid by Medicare and/or Medi-Cal, to induce such physicians to prescribe PPS PAP devices or supplies to such patients, for which PPS was paid by the Medicare and /or Medi-Cal programs. PPS knowingly submitted claims for such payments that PPS knew were generated by this arrangement. PPS management knew about and encouraged such conduct by its PCCs to increase sales of home oxygen equipment and service. Such conduct violated the Anti-Kickback Statute, 42 USC § 1320a–7b(2).

172. As set forth in more detail in the preceding paragraphs, PPS knowingly solicited and received valuable remuneration, including prescriptions for PAP devices or supplies, directly or indirectly, in return for referring Medicare or Medi-Cal patients or recommending that physicians refer Medicare or Medi-Cal patients to physicians or clinics, including the Sleep Test Defendants, to perform sleep testing on such patients that were paid for by the Medicare and/or Medi-Cal programs. PPS knowingly submitted claims for such payments that PPS knew were generated by this arrangement. PPS management knew about and encouraged such conduct by

its PCCs to increase sales of home oxygen equipment and service. Such conduct violated the Anti-Kickback Statute, 42 USC § 1320a–7b(1).

173. Through submission of Form CMS-855S ("PPS Medicare Certification"), PPS certified that it would comply with Medicare laws, regulations and program instructions that apply to it, and that it would immediately notify the National Supplier Clearinghouse if any information in its Certification was not true, correct, or complete, *i.e.* that it did not comply with the Medicare laws, regulations and program instructions applicable to it. In the PPS Medicare Certification, the authorized PPS signatory specifically agreed" "I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare."

174. Through submission of the Medi-Cal Provider Agreement, DHCS Form 6208 ("PPS Medi-Cal Certification"), PPS certified that it would comply with "all federal laws and regulations governing and regulating Medicaid providers" that apply to it, including the Anti-Kickback Statute). In signing the Provider Agreement, PPS agreed "that compliance with the provisions of this agreement is a condition precedent to payment to provider."

175. PPS knowingly violated the AKS, the PPS Medicare Certification and the PPS Medi-Cal Certification by training, directing and encouraging its PCCs to engage in the illegal kickback arrangements with the Sleep Test Defendants, among other physicians and clinics performing PSG sleep tests, set forth in the preceding paragraphs.

176. PPS' knowing violation of the AKS and knowingly false PPS Medicare Certification was material to its payment for PAP devices and supplies under the Medicare

program. PPS' knowing violation of the AKS and knowingly false PPS Medi-Cal Certification was material to its payment for PAP devices and supplies under the Medi-Cal program.

177. Claims submitted by PPS to any federal health care program or the Medi-Cal program from at least March 2009 through January 2010 as a result of a prescription written by physicians associated with the Sleep Test Defendants are tainted by the illegal kickbacks described above, including, but not limited to, claims for PAP devices and supplies identified by Health Care Procedure (HCPCS) Codes E0470, E0471, E0601, E0561, E0562, A4604, A7027, A7028, A7029, A7030, A7031, A7032, 7033, A7034, A7035, A7036, A7037, A7038, A7039, A7044, A7045, and A7046. Each claim submitted by PPS on CMS Form 1500 to CMS, though its carrier, contains electronic data that includes the patient's name and identification number, dates of service, the Current Procedure Terminology (CPT) Codes or HCPCS Codes, the amount billed, the identification of the physician referring the patient, the date of the claim, and the date and amount of each payment to PPS. PPS is in possession of the relevant CMS Form 1500s submitted for such claims and the backup documentation required by the 2009 PAP LCD, including an "order for each item billed … signed and dated by the treating physician." PPS also is in possession of corresponding Medi-Cal or TRICARE forms used to make claims for PAP devices and supplies described in this paragraph, and required backup documentation, including a Treatment Authorization Request ("TAR") for each claim.

178. As set forth above, PPS PCCs provided physicians with free use of PPS-owned pulse oximeters to conduct pulse oximetry tests on Medicare and Medi-Cal patients, for which such physicians were paid or had the opportunity to be paid by Medicare and/or Medi-Cal programs, in exchange for and to induce such physicians to prepare prescriptions and CMNs for PPS home oxygen equipment and supplies that were paid for by the Medicare and/or Medi-Cal

programs. PPS knowingly submitted claims for such payments that PPS knew were generated by this arrangement. PPS management knew about and encouraged such conduct by its PCCs to increase sales of home oxygen equipment and supplies. Such conduct violated the Anti-Kickback Statute, 42 USC § 1320a–7b(2).

179. PPS knowingly violated the AKS, the PPS Medicare Certification and the PPS Medi-Cal Certification by training, directing and encouraging its PCCs to engage in the illegal kickback arrangements with physicians and their staff receiving the "loaner" oximeters as set forth in the preceding paragraphs.

180. PPS' knowing violation of the AKS and knowingly false PPS Medicare Certification was material to its payment for home oxygen equipment and supplies under the Medicare program. PPS' knowing violation of the AKS and knowingly false PPS Medi-Cal Certification was material to its payment for home oxygen equipment and supplies under the Medi-Cal program.

181. Claims submitted by PPS to any federal health care program or the Medi-Cal program from at least March 2009 through January 2010 as a result of a prescription and/or CMN signed by physicians who received free use of PPS-owned pulse oximeters is tainted by the illegal kickbacks described above, including, but not limited to, claims for home oxygen equipment and supplies identified by HCPCS Codes E0424, E0425, E0430, E0431, E0434, E0435, E0439, E0440, E0441, E0442, E0443, E0444, E0445, E1390, E1391, E1392, E1405, E1406, K0738, A4575, A4606, A4608, A4616, A4617, A4619, A4620, A7525, A9900, E0455, E0555, E0580, E1353, E1354, E1355, E1356, E1357 and E1358. Each claim submitted by PPS on CMS Form 1500 to CMS, though its carrier, contains electronic data that includes the patient's name and identification number, dates of service, the CPT Codes or HCPCS Codes, the

amount billed, the identification of the physician referring the patient, the date of the claim, and the date and amount of each payment to PPS. PPS is in possession of the relevant CMS Form 1500s submitted for such claims and the documentation required by the 2009 Oxygen LCD for each such claim, including an "order for each item billed ... signed and dated by the treating physician," a CMN signed and dated by the treating physician, a copy of the qualifying pulse oximetry report, and proof of delivery. PPS also is in possession of corresponding Medi-Cal or TRICARE forms used to make claims for home oxygen equipment and supplies, and required backup documentation, including a Treatment Authorization Request ("TAR") for each claim.

182. As set forth above, Medicare and Medi-Cal patients may only receive home oxygen equipment and service paid for by the Medicare and/or Medi-Cal programs if the results of a blood gas study, including pulse oximetry testing, qualify them as needing oxygen therapy. PPS PCCs manipulated pulse oximetry testing to qualify Medicare and Medi-Cal patients for home oxygen by exercising such patients to desaturate the oxygen in their blood before either a PPS PCC or physician's staff conducted a pulse oximetry test that was falsely reported as an At-Rest pulse oximetry test. The false test results were recorded in the patients' medical records and relied upon by physicians to write both prescriptions and CMNs for PPS home oxygen equipment and supplies paid for by the Medicare and/or Medi-Cal programs. PPS knowingly submitted claims for such payment that relied upon the false pulse oximetry testing results incorporated into the physicians' prescriptions and CMNs. PPS management knew about and encouraged such conduct to increase sales of home oxygen equipment and service.

183. PPS knowingly created false records, submitted false claims, and violated the PPS Medicare Certification and the PPS Medi-Cal Certification by training, directing and

encouraging its PCCs to exercise patients immediately before conducting a purported "At-Rest" pulse oximetry test as set forth in the preceding paragraphs.

184. PPS' knowing falsification of At-Rest pulse oximetry testing results, knowingly false PPS Medicare Certification, and knowingly false PPS Medi-Cal Certification were material to receiving payments for home oxygen equipment and supplies under the Medicare program and/or the Medi-Cal program.

185. Claims submitted by PPS to any federal health care program or the Medi-Cal program from at least March 2009 through January 2010 as a result of a prescription and/or CMN signed by physicians who relied upon reported "At-Rest" pulse oximetry results for a patient exercised by PPS PCCs immediately before such test is false and fraudulent including, but not limited to, claims for home oxygen equipment and supplies identified by HCPCS Codes E0424, E0425, E0430, E0431, E0434, E0435, E0439, E0440, E0441, E0442, E0443, E0444, E0445, E1390, E1391, E1392, E1405, E1406, K0738, A4575, A4606, A4608, A4616, A4617, A4619, A4620, A7525, A9900, E0455, E0555, E0580, E1353, E1354, E1355, E1356, E1357 and E1358. Each claim submitted by PPS on CMS Form 1500 to CMS, though its carrier, contains electronic data that includes the patient's name and identification number, dates of service, the CPT Codes or HCPCS Codes, the amount billed, the identification of the physician referring the patient, the date of the claim, and the date and amount of each payment to PPS. PPS is in possession of the relevant CMS Form 1500s submitted for such claims and the documentation required by the 2009 Oxygen LCD for each such claim, including an "order for each item billed … signed and dated by the treating physician," a CMN signed and dated by the treating physician, a copy of the qualifying pulse oximetry report, and proof of delivery. PPS also is in possession of corresponding Medi-Cal or TRICARE forms used to make claims for home

oxygen equipment and supplies, and required backup documentation, including a Treatment Authorization Request ("TAR") for each claim.

186. As set forth above, PPS knowingly violated the PPS Medicare Certification by training, directing and encouraging its PCCs to perform pulse oximetry tests on Medicare patients, which violated the Oxygen NCD, Transmittal 173, and the Oxygen LCD.

187. As set forth above, PPS knowingly violated the PPS Medicare Certification by training, directing and encouraging its PCCs to select the IDTF that was supposed to supervise overnight home pulse oximetry testing on Medicare patients, which violated the Oxygen NCD, Transmittal 173, and the Oxygen LCD.

188. As set forth above, PPS knowingly violated the PPS Medicare Certification by training, directing and encouraging its PCCs to perform overnight home pulse oximetry tests on Medicare patients, without a physician's order for such a test and before an IDTF was requested by a physician to direct such a test, which violated the Oxygen NCD, Transmittal 173, and the Oxygen LCD.

189. As set forth above, PPS knowingly violated the PPS Medicare Certification by training, directing and encouraging its PCCs to instruct and show Medicare patients how to perform overnight home pulse oximetry tests, which violated the Oxygen NCD, Transmittal 173, and the Oxygen LCD.

190. As set forth above, PPS knowingly violated the PPS Medicare Certification by training, directing and encouraging its PCCs to access the data from overnight home pulse oximetry testing, and then later sending that same data to an IDTF, which violated the Oxygen NCD, Transmittal 173, and the Oxygen LCD.

191. As set forth above, PPS knowingly violated the PPS Medicare Certification by training, directing and encouraging its PCCs to solicit Medicare patients in physician waiting rooms, hospitals, clinics and their homes to urge their physicians to conduct pulse oximetry tests on them, with the purpose of selling PPS home oxygen equipment and supplies, in violation of the Noridian June 2006 Bulletin.

192. As set forth above, PPS knowingly violated the PPS Medicare Certification by training, directing and encouraging its PCCs to solicit physicians in their offices, hospitals, and clinics to conduct pulse oximetry tests on Medicare patients with the purpose of selling PPS home oxygen equipment and supplies, in violation of the Noridian June 2006 Bulletin.

193. As set forth above, PPS knowingly violated the PPS Medicare Certification by training, directing and encouraging its employees to provide physicians who have prescribed Medicare patients PPS home oxygen equipment and supplies with a partially completed CMN accompanied by information relating to the beneficiary's medical condition and suggested text for the physician to incorporate in Section B of the CMN, which violated 42 U.S.C. Section 1395m(j)(2)(A), the Form CMS-484 Instructions, the Oxygen NCD, and the Noridian DME MAC Jurisdiction D Supplier Manual, Chapter 4, regarding the Certificate of Medical Necessity/DME Information Form.

194. Claims submitted by PPS to any federal health care program from at least March 2009 through January 2010 as a result of a prescription and/or CMN signed by physicians affected by the foregoing PPS violations of the PPS Medicare Certification is false and fraudulent including, but not limited to, claims for home oxygen equipment and supplies identified by HCPCS Codes E0424, E0425, E0430, E0431, E0434, E0435, E0439, E0440, E0441, E0442, E0443, E0444, E0445, E1390, E1391, E1392, E1405, E1406, K0738, A4575,

A4606, A4608, A4616, A4617, A4619, A4620, A7525, A9900, E0455, E0555, E0580, E1353, E1354, E1355, E1356, E1357 and E1358. Each claim submitted by PPS on CMS Form 1500 to CMS, though its carrier, contains electronic data that includes the patient's name and identification number, dates of service, the CPT Codes or HCPCS Codes, the amount billed, the identification of the physician referring the patient, the date of the claim, and the date and amount of each payment to PPS. PPS is in possession of the relevant CMS Form 1500s submitted for such claims and the documentation required by the 2009 Oxygen LCD for each such claim, including an "order for each item billed … signed and dated by the treating physician," a CMN signed and dated by the treating physician, a copy of the qualifying pulse oximetry report, and proof of delivery. PPS also is in possession of corresponding Medi-Cal or TRICARE forms used to make claims for home oxygen equipment and supplies, and required backup documentation, including a Treatment Authorization Request ("TAR") for each claim.

195. As set forth above, the Sleep Test Defendants knowingly offered PPS valuable remuneration consisting of prescriptions for Medicare and Medi-Cal patients to receive PPS PAP devices and supplies, for which PPS was paid by the Medicare and/or Medi-Cal programs, to induce PPS to refer or recommend Medicare and Medi-Cal patients to the Sleep Test Defendants for PSG sleep testing, for which the Sleep Test Defendants were paid by the Medicare and /or Medi-Cal programs. The Sleep Test Defendants knowingly submitted claims for such payments that they knew were generated by this arrangement. Such conduct violated the Anti-Kickback Statute, 42 USC § 1320a–7b(2).

196. As set forth above, the Sleep Test Defendants knowingly solicited and received valuable remuneration from PPS, including referrals and recommendation for the Sleep Test Defendants to perform sleep tests on Medicare and Medi-Cal patients, for which the Sleep Test

Defendants were paid by the Medicare and /or Medi-Cal programs, in return for the Sleep Test Defendants writing prescriptions for Medicare and Medi-Cal patients to receive PPS PAP devices and supplies, for which PPS was paid -by the Medicare and/or Medi-Cal programs. The Sleep Test Defendants knowingly submitted claims for such payments that they knew were generated by this arrangement. Such conduct violated the Anti-Kickback Statute, 42 USC § 1320a–7b(1).

197. Through submission of Form CMS-855B or Form CMS-855I, depending upon their nature ("Sleep Test Defendants' Medicare Certifications"), the Sleep Test Defendants certified that they would comply with Medicare laws, regulations and program instructions that apply to them, and that they would immediately notify the National Supplier Clearinghouse if any information in their Certifications was not true, correct, or complete, *i.e.* that they did not comply with the Medicare laws, regulations and program instructions applicable to them. In the Sleep Test Defendants Medicare Certifications, the authorized signatory specifically agreed: "I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare."

198. Through submission of the Medi-Cal Provider Agreement, DHCS Form 6208 ("Sleep Test Defendants Medi-Cal Certification"), the Sleep Test Defendants certified that they would comply with "all federal laws and regulations governing and regulating Medicaid providers" that applied to them, including the Anti-Kickback Statute. In signing the Provider Agreement, each Sleep Test Defendant agreed "that compliance with the provisions of this agreement is a condition precedent to payment to provider."

199. The Sleep Test Defendants knowingly violated the AKS, the Sleep Test Defendants Medicare Certifications and the Sleep Test Defendants Medi-Cal Certifications by engaging, and encouraging their staff to engage, in the illegal kickback arrangements with PPS set forth in the preceding paragraphs.

200. Sleep Test Defendants' knowing violations of the AKS and knowingly false Sleep Test Defendants Medicare Certifications were material to their payment for PSG sleep tests under the Medicare program. The Sleep Test Defendants' knowing violations of the AKS and knowingly false Sleep Test Defendants Medi-Cal Certifications were material to their payment for PSG sleep tests under the Medi-Cal program.

201. Claims submitted by Sleep Test Defendants to any federal health care program or the Medi-Cal program from at least March 2009 through January 2010 as a result of a prescription signed by physicians served by PPS is tainted by the illegal kickbacks described herein, including, but not limited to, claims for PSG sleep test identified by CPT Codes 95805, 95806, 95807, 95808, 95810, 95811, 94375, and 94660. Each claim submitted by PPS on CMS Form 1500 to CMS, though its carrier, contains electronic data that includes the patient's name and identification number, dates of service, the CPT Codes, the amount billed, the identification of the physician referring the patient, the date of the claim, and the date and amount of each payment to the submitting Sleep Test Defendant. Each Sleep Test Defendant is in possession of the relevant CMS Form 1500s submitted for such claims and the required backup documentation. Each Sleep Test Defendant also is in possession of corresponding Medi-Cal or TRICARE forms used to make claims for PSG sleep tests and required backup documentation.

202. Upon information and belief, SLSDC-associated physicians, including Dr. RS Rajah and Dr. Paul Robinson, billed Medicare for a "face-to-face clinical re-evaluation by the

treating physician" of patients receiving Medicare-paid PAP device coverage when Kevin Angelo, the SLSDC Clinical Director, and not themselves, met with such patients. Such claims submitted to Medicare from at least March 2009 through January 2010 were false and fraudulent. SLSDC and/or its affiliated physicians, including Dr. RS Rajah and Dr. Paul Robinson, are in possession of the relevant CMS Form 1500s submitted for such claims and the required backup documentation, as well as corresponding forms submitted to Medi-Cal or TRICARE for such services. The 2009 PAP LCD requires that: "Physicians shall document the face-to-face clinical evaluations and re-evaluations in a detailed narrative note in their charts in the format that they use for other entries."

203. Continued prescriptions of PAP devices by SLSDC-associated physicians, including Dr. RS Rajah and Dr. Paul Robinson, for Medicare patients without conducting the "face-to-face clinical re-evaluation by the treating physician" required by the 2009 PAP LCD, violated their Medicare Certifications and caused false and fraudulent claims to be submitted to Medicare for continued coverage PAP devices and supplies provided by PPS and billed to Medicare pursuant to HCPS Codes E0470, E0471, E0601, E0561, E0562, A4604, A7027, A7028, A7029, A7030, A7031, A7032, 7033, A7034, A7035, A7036, A7037, A7038, A7039, A7044, A7045, and A7046. PPS is in possession of the relevant CMS Form 1500s submitted for such claims and the backup documentation required by the 2009 PAP LCD, including an "order for each item billed … signed and dated by the treating physician." PPS also is in possession of corresponding Medi-Cal or TRICARE forms used to make claims for PAP devices and supplies described in this paragraph, and required backup documentation.

204. Defendants acted with actual knowledge, deliberate ignorance, or reckless disregard of the law when submitting their claims to the federal and California health care

programs for reimbursement for equipment and services rendered, as described above, in violation of the False Claims Act. Defendants were not entitled to be paid for these claims, and the United States and/or the State of California would not have paid these claims, or would have recouped the money paid for these claims, had the government known that the claims were false and fraudulent as described above.

205. As a result of Defendants' false and fraudulent claims for reimbursement, the United States and the State of California reimbursed Defendants for claims in connection with equipment and supplies provided in an amount to be determined through discovery.

Count I

Against the PPS Defendants

Violation of the False Claims Act, 31 U.S.C. §§ 3729(a)(1)(A), (B),(C), (G)

206. Relator repeats and incorporates herein by reference the allegations of all previous paragraphs as if fully stated herein.

207. Through the conduct set forth in the preceding paragraphs, the PPS Defendants knowingly presented and caused to be presented false and fraudulent claims to the federal and California health care programs for payment for PAP devices and supplies, and home oxygen equipment and supplies, in violation of 31 U.S.C. § 3729(a)(1)(A).

208. Through the conduct set forth in the preceding paragraphs, the PPS Defendants knowingly made, used and caused to be made false records and statements that were material to false and fraudulent claims submitted to federal and California health care programs for payment for PAP devices and supplies, and home oxygen equipment and supplies, in violation of 31 U.S.C. § 3729(a)(1)(B).

209. Through the conduct set forth in the preceding paragraphs, the PPS Defendants conspired with certain physicians to knowingly cause to present false and fraudulent claims to federal and California health care programs, and to cause to be made false records that were material to false and fraudulent claims submitted to federal and California health care programs for payment for PAP devices and supplies, and home oxygen equipment and supplies, in violation of 31 U.S.C. § 3729(a)(1)(C).

210. Through the conduct set forth in the preceding paragraphs, the PPS Defendants knowingly made and used or caused to be made or used, false records or false statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States in violation of 31 U.S.C. § 3729(a)(1)(G).

211. Through the conduct set forth in the preceding paragraphs, the PPS Defendants also knowingly violated the PPS Medicare Certification, which expressly conditioned payment on continued compliance with Medicare laws, regulations and program instructions that applied to it. Through the conduct set forth in the preceding paragraphs, the PPS Defendants also knowingly violated the PPS Medi-Cal Certification, which expressly conditioned payment on continued compliance with Medicaid laws that applied to it, and submitted false and fraudulent claims for payment for PAP devices and supplies, and home oxygen equipment and supplies in violation of 31 U.S.C. §§ 3729(a)(1)(A), (B), (C) and (G).

212. Form CMS 855S and the Medi-Cal Provider Agreement conditions participation in the Medicare and Medi-Cal programs, respectively, on compliance with specified federal Medicare and Medicaid statutes and regulations. A provider who fails to comply with these statutes and regulations is not entitled to payment for services rendered to Medicare or Medicaid patients. By submitting a claim for Medicare or Medicaid reimbursement, PPS implicitly

certified that the submitted claim was eligible for Medicare or Medicaid reimbursement and that PPS was in compliance with its PPS Medicare Certification, PPS Medi-Cal Certification, and federal Medicare and Medicaid requirements. Through the conduct set forth in the preceding paragraphs, the PPS Defendants knew such implied certification was false and fraudulent, and that its claims for payment for PAP devices and supplies, and home oxygen equipment and supplies violated 31 U.S.C. §§ 3729(a)(1)(A), (B), (C) and (G).

213. As a result of the foregoing acts of the PPS Defendants, the United States government, unaware of the falsity of the records, statements and claims made or caused to be made by the PPS Defendants, provided payments for PAP devices and supplies, and home oxygen equipment and supplies that they would not have if the PPS Defendants had not engaged in such conduct.

214. Relator cannot at this time identify with specificity all of the false claims for payment that were caused by the PPS Defendants' foregoing conduct. Relator has no control over or dealings with the PPS Defendants and has no access to the records in their possession.

215. By reason of the PPS Defendants' foregoing conduct, the United States has been damaged in substantial amount to be determined at trial.

216. By virtue of the false or fraudulent claims made by the PPS Defendants, the United States has suffered damages and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each violation.

Count II

Against the Sleep Test Defendants

Violation of the False Claims Act, 31 U.S.C. §§ 3729(a)(1)(A), (B), (C), (G)

217. Relator repeats and incorporates herein by reference the allegations of all previous paragraphs as if fully stated herein.

218. Through the conduct set forth in the preceding paragraphs, the Sleep Test Defendants knowingly presented and caused to be presented false and fraudulent claims to federal and California health care programs for payment for PSG sleep tests in violation of 31 U.S.C. § 3729(a)(1)(A).

219. Through the conduct set forth in the preceding paragraphs, the Sleep Test Defendants knowingly made, used and caused to be made false records and statements that were material to false and fraudulent claims submitted to federal and California health care programs for payment for PSG sleep tests in violation of 31 U.S.C. § 3729(a)(1)(B).

220. Through the conduct set forth in the preceding paragraphs, the Sleep Test Defendants conspired with certain physicians to knowingly cause to present false and fraudulent claims to the federal and California health care programs, and to cause to be made false records that were material to false and fraudulent claims submitted to the federal and California health care programs for payment for PSG sleep tests in violation of 31 U.S.C. § 3729(a)(1)(C).

221. Through the conduct set forth in the preceding paragraphs, the Sleep Test Defendants knowingly made and used or caused to be made or used, false records or false statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States in violation of 31 U.S.C. § 3729(a)(1)(G).

222. Through the conduct set forth in the preceding paragraphs, the Sleep Test Defendants also knowingly violated the Sleep Test Medicare Certification, which expressly conditioned payment on continued compliance with Medicare laws, regulations and program instructions that applied to it. Through the conduct set forth in the preceding paragraphs, the

Sleep Test Defendants also knowingly violated the Sleep Test Medi-Cal Certification, which expressly conditioned payment on continued compliance with Medicaid laws that applied to it, and submitted false and fraudulent claims for payment to federal and California health care programs for PSG sleep tests in violation of 31 U.S.C. §§ 3729(a)(1)(A), (B), (C) and (G).

223. Form CMS 855I, Form CMS-855B and the Medi-Cal Provider Agreement each conditions participation in the Medicare and Medi-Cal programs, respectively, on compliance with specified federal Medicare and Medicaid statutes and regulations. A provider who fails to comply with these statutes and regulations is not entitled to payment for services rendered to Medicare or Medicaid patients. By submitting a claim for Medicare or Medicaid reimbursement, the Sleep Test Defendants implicitly certified that the submitted claim was eligible for Medicare or Medicaid reimbursement and that the submitter was in compliance with its Medicare Certification, its Medi-Cal Certification, and federal Medicare and Medicaid requirements. Through the conduct set forth in the preceding paragraphs, the Sleep Test Defendants knew such implied certifications were false and fraudulent, and that their claims for payment to federal and California health care programs for PSG sleep tests violated 31 U.S.C. §§ 3729(a)(1)(A), (B), (C) and (G).

224. As a result of the foregoing acts of the Sleep Test Defendants, the United States government, unaware of the falsity of the records, statements and claims made or caused to be made by the Sleep Test Defendants, provided payments for PSG sleep tests that it would not have if the Sleep Test Defendants had not engaged in such conduct.

225. Relator cannot at this time specifically identify all of the false claims for payment that were caused by the Sleep Test Defendants' foregoing conduct. Relator has no control over or dealings with the Sleep Test Defendants and has no access to the records in their possession.

226. By reason of the Sleep Test Defendants' foregoing conduct, the United States has been damaged in substantial amount to be determined at trial.

227. By virtue of the false or fraudulent claims made by the Sleep Test Defendants, the United States has suffered damages and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each violation.

Count III

Against the PPS Defendants

California False Claims Act, California Gov. Code §§ 12651(a)(1),(2), (3), (7)

228. Relator repeats and incorporates herein by reference the allegations of all previous paragraphs as if fully stated herein.

229. Through the conduct set forth above, the PPS Defendants knowingly presented and caused to be presented false and fraudulent claims to the Medi-Cal program for payment for PAP devices and supplies, and home oxygen equipment and supplies, in violation of California Gov. Code § 12651(a)(1).

230. Through the conduct set forth above, the PPS Defendants knowingly made, used and caused to be made false records and statements that were material to false and fraudulent claims to the Medi-Cal program for payment for PAP devices and supplies, and home oxygen equipment and supplies, in violation of California Gov. Code § 12651(a)(2).

231. Through the conduct set forth above, the PPS Defendants conspired with certain physicians to knowingly cause to present false and fraudulent claims to the Medi-Cal program, and to cause to be made false records that were material to false and fraudulent claims to the Medi-Cal program for payment for PAP devices and supplies, and home oxygen equipment and supplies, in violation of California Gov. Code § 12651(a)(3).

232. Through the conduct above, the PPS Defendants knowingly made and used or caused to be made or used, false records or false statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of California in violation of California Gov. Code § 12651(a)(7).

233. Through the conduct set forth above, the PPS Defendants also knowingly violated the PPS Medi-Cal Certification, which expressly conditioned payment on continued compliance with Medicaid laws that applied to it, and submitted false and fraudulent claims for payment for PAP devices and supplies, and home oxygen equipment and supplies in violation of California Gov. Code § 12651(a)(1), (2), (3), (7).

234. The Medi-Cal Provider Agreement conditions participation in the Medi-Cal program on compliance with specified federal Medicaid statutes and regulations. A provider who fails to comply with these statutes and regulations is not entitled to payment for services rendered to Medicaid patients. By submitting a claim for Medicaid reimbursement, PPS implicitly certified that the submitted claim was eligible for Medicaid reimbursement and that PPS was in compliance with its PPS Medi-Cal Certification and federal Medicaid requirements. Through the conduct set forth in the preceding paragraphs, the PPS Defendants knew such implied certification was false and fraudulent, and that its claims for payment for PAP devices and supplies, and home oxygen equipment and supplies violated California Gov. Code § 12651(a)(1), (2), (3), (7).

235. As a result of the foregoing acts of the PPS Defendants, the State of California government, unaware of the falsity of the records, statements and claims made or caused to be made by the PPS Defendants, provided payments for PAP devices and supplies, and home

oxygen equipment and supplies that they would not have if the PPS Defendants had not engaged in such conduct.

236. Relator cannot at this time specifically identify all of the false claims for payment that were caused by the PPS Defendants' foregoing conduct. Relator has no control over or dealings with the PPS Defendants and has no access to the records in their possession.

237. By reason of the PPS Defendants' foregoing conduct, the State of California has been damaged in substantial amount to be determined at trial.

238. By virtue of the false or fraudulent claims made by the PPS Defendants, the State of California has suffered damages and therefore is entitled to multiple damages under the California False Claims Act, to be determined at trial, plus the maximum civil penalty of $10,000 for each violation.

Count IV

Against the Sleep Test Defendants

California False Claims Act, California Gov. Code §§ 12651(a)(1), (2), (3), (7)

239. Relator repeats and incorporates herein by reference the allegations of all previous paragraphs as if fully stated herein.

240. Through the conduct set forth above, the Sleep Test Defendants knowingly presented and caused to be presented false and fraudulent claims to the Medi-Cal program for payment for PSG sleep tests in violation of California Gov. Code § 12651(a)(1).

241. Through the conduct set forth above, the Sleep Test Defendants knowingly made, used and caused to be made false records and statements that were material to false and fraudulent claims to the Medi-Cal program for payment for PSG sleep tests in violation of California Gov. Code § 12651(a)(2).

242. Through the conduct set forth above, the Sleep Test Defendants conspired with certain physicians to knowingly cause to present false and fraudulent claims to the Medi-Cal program, and to cause to be made false records that were material to false and fraudulent claims to the Medi-Cal program for payment for PSG sleep tests in violation of California Gov. Code § 12651(a)(3).

243. Through the conduct set forth above, the Sleep Test Defendants knowingly made and used or caused to be made or used, false records or false statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of California in violation of California Gov. Code § 12651(a)(7).

244. Through the conduct set forth above, the Sleep Test Defendants also knowingly violated the Sleep Test Defendants Medi-Cal Certification, which expressly conditioned payment on continued compliance with Medicaid laws that applied to it, and submitted false and fraudulent claims for payment for PSG sleep tests in violation of California Gov. Code § 12651(a)(1), (2), (3), (7).

245. The Medi-Cal Provider Agreement conditions participation in the Medi-Cal program on compliance with federal Medicaid statutes and regulations. A provider who fails to comply with these statutes and regulations is not entitled to payment for services rendered to Medi-Cal patients. By submitting a claim for Medi-Cal reimbursement, the Sleep Test Defendants implicitly certified that the submitted claim was eligible for Medi-Cal reimbursement and that the submitter was in compliance with its Medi-Cal Certification, and federal Medicaid requirements. Through the conduct set forth in the preceding paragraphs, the Sleep Test Defendants knew such implied certifications were false and fraudulent, and that their claims for payment for PSG sleep tests violated California Gov. Code § 12651(a)(1), (2), (3), (7).

246. As a result of the foregoing acts of the Sleep Test Defendants, the State of California government, unaware of the falsity of the records, statements and claims made or caused to be made by the Sleep Test Defendants, provided payments for PSG sleep tests that it would not have if the Sleep Test Defendants had not engaged in such conduct.

247. Relator cannot at this time specifically identify all of the false claims for payment that were caused by the Sleep Test Defendants' foregoing conduct. Relator has no control over or dealings with the Sleep Test Defendants and has no access to the records in their possession.

248. By reason of the Sleep Test Defendants' foregoing conduct, the State of California has been damaged in substantial amount to be determined at trial.

249. By virtue of the false or fraudulent claims made by the Sleep Test Defendants, the State of California has suffered damages and therefore is entitled to multiple damages under the California False Claims Act, to be determined at trial, plus a maximum civil penalty of $10,000 for each violation.

Count V

Against SLSDC

Violation of the False Claims Act, 31 U.S.C. §§ 3729(a)(1)(A), (B), (C), (G)

250. Relator repeats and incorporates herein by reference the allegations of all previous paragraphs as if fully stated herein.

251. Through the conduct set forth in the preceding paragraphs, and on information and belief, physicians associated with Defendant SLSDC, including Dr. R.S. Rajah, and Dr. Paul Robinson, knowingly presented and caused to be presented false and fraudulent claims to the Medicare program for payment for PAP re-certification visits in violation of 31 U.S.C. § 3729(a)(1)(A).

252. Through the conduct set forth in the preceding paragraphs, and on information and belief, physicians associated with Defendant SLSDC, including Dr. R.S. Rajah, and Dr. Paul Robinson, knowingly made, used and caused to be made false records and statements that were material to false and fraudulent claims to the Medicare program for payment for PAP re-certification visits and PAP devices and supplies in violation of 31 U.S.C. § 3729(a)(1)(B).

253. Through the conduct set forth in the preceding paragraphs, physicians associated with Defendant SLSDC, including Dr. R.S. Rajah, and Dr. Paul Robinson, conspired to knowingly cause to present false and fraudulent claims to the Medicare program, and to cause to be made false records that were material to false and fraudulent claims to the Medicare program for payment for PAP re-certification visits and PAP devices and supplies in violation of 31 U.S.C. § 3729(a)(1)(C).

254. Through the conduct set forth in the preceding paragraphs, physicians associated with Defendant SLSDC, including Dr. R.S. Rajah, and Dr. Paul Robinson, knowingly made and used or caused to be made or used, false records or false statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States in violation of 31 U.S.C. § 3729(a)(1)(G).

255. Through the conduct set forth in the preceding paragraphs, physicians associated with Defendant SLSDC, including Dr. R.S. Rajah, and Dr. Paul Robinson, also knowingly violated their Form CMS 855I or CMS 855B Medicare Certifications, which expressly conditioned payment on continued compliance with Medicare laws, regulations and program instructions that applied to them, and submitted false and fraudulent claims for payment for PAP recertification visits in violation of 31 U.S.C. §§ 3729(a)(1)(A), and caused to be made false

claims for and records material to claims for payment for continued coverage of PAP devices and supplies in violation of 31 U.S.C. §§ 3729(a)(1)(A) and (B).

256. Each of Form CMS 855I and Form CMS-855B conditions participation in the Medicare program on compliance with Medicare laws, regulations and program instructions. A provider who fails to so comply is not entitled to payment for services rendered to Medicare patients. By submitting a claim for Medicare reimbursement, Defendant SLSDC implicitly certified that the submitted claim was eligible for Medicare reimbursement and that the submitter was in compliance with its Medicare Certification. Through the conduct set forth in the preceding paragraphs, Defendant SLSDC knew such implied certifications were false and fraudulent, and that its claims for payment for PAP re-certification visits violated 31 U.S.C. §§ 3729(a)(1)(A) and (B).

257. As a result of the foregoing acts of physicians associated with Defendant SLSDC, including Dr. R.S. Rajah, and Dr. Paul Robinson, the United States government, unaware of the falsity of the records, statements and claims made or caused to be made by such physicians, provided payments for PAP re-certification visits and continued coverage of PAP devices and supplies that it would not have if such physicians had not engaged in such conduct.

258. Relator cannot at this time specifically identify all of the false claims for payment that were caused by the foregoing conduct of Defendant SLSDC. Relator has no control over or dealings with Defendant SLSDC and its associated physicians, and has no access to the records in their possession.

259. By reason of the foregoing conduct of Defendant SLSDC, the United States has been damaged in substantial amount to be determined at trial.

260. By virtue of the false or fraudulent claims made by Defendant SLSDC, the United States has suffered damages and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each violation.

Count VI

Retaliation

False Claims Act 31 U.S.C. § 3730(h)

261. Relator repeats and incorporates herein by reference the allegations of all previous paragraphs as if fully stated herein.

262. Beginning in September 2009, Relator alerted his manager, Karen Vickrey, to his concern that PPS was violating Medicare laws through its arrangements with various sleep test clinics. His actions were fully lawful, and are protected pursuant to 31 U.S.C. § 3730(h), the federal False Claim Act's anti-retaliation action.

263. On January 27, 2010, Relator was terminated from his position as a PCC for PPS for pretextual reasons. PPS raised "questions" about Relator having falsified a physician's signature on CMNs; however, there was no factual basis for such "questions."

264. On information and belief, Relator was fired because Relator had raised his concerns that PPS' arrangements with various sleep test clinics violated Medicare laws.

Prayer for Relief

WHEREFORE, Relator Manuel Alcaine requests the judgment be entered in his favor and against Defendants as follows:

a. On the First, Second, and Fifth Counts, under the Federal False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law;

b. On the Third and Fourth Counts, under the California False Claims Act, for the amount of the State of California's damages, trebled as required by law, and such civil penalties as are required by law;

c. On the Sixth Count, under the Federal False Claims Act, for Alcaine's reinstatement with the same seniority status such that he would have had but for the discrimination, two times the amount of back pay, interest on the back pay, and compensation for special damages sustained as a result of the discrimination, as shown as trial, including litigation costs and reasonable attorneys' fees;

d. that Defendants be enjoined from violating the Federal False Claims Act, the California False Claims Act, the Anti-Kickback Statute, and the Medicare program instructions set forth herein;

e. that Relator, as a *qui tam* Plaintiff, be awarded the maximum amount allowed pursuant to Federal False Claims Act and the California False Claims Act and/or any other provision of law;

f. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

g. that Relator have such further relief that this Court deems just and proper.

DATED: October 12, 2010 WORK/ENVIRONMENT LAW GROUP

By: [signature]
Richard W. Raushenbush
Attorneys for Plaintiff/Relator Manuel Alcaine